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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,234	01/13/2005	Satoshi Yonehara	10873.1574USWO	8752

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EXAMINER	
ARIANI, KADE	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
12/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,234	YONEHARA ET AL.	
	Examiner	Art Unit	
	KADE ARIANI	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-15* is/are rejected.

7)☒ Claim(s) *11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/04/2007 and 08/08/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

In view of the appeal brief filed on 08/20/2008, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Michael G. Wityshyn/

Supervisory Patent Examiner, Art Unit 1651

Applicant's arguments with respect to claims 8, and 10-15 have been fully considered but are moot in view of the new ground(s) of rejection.

Claim Objection

Claim 11 is objected to because of the following informalities:

An indefinite article ("a" or "an") is used before singular nouns that refer to any member of a group, and a definite article ("the") is used before singular and plural nouns that refer back to a particular member of a group.

In claim 11 the word "metalloproteinase" lacks the proper grammatical article "a".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, and 10-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 15 and its dependent claims 8 and 10-14, Applicant claims a "method of measuring a glycated protein", however, from the way the claims have been written it is unclear what exactly is it that the Applicant is trying to measure by this method. As written, it would appear applicant is trying to assess the size of the protein but that would not appear to be applicant's invention. There are many characteristics that can be

measured of a glycated protein and the claims fail to particularly point out and distinctly set forth the subject matter which applicant regards as the invention, and are thus indefinite. Applicant should amend to particularly point out and distinctly claim the invention.

Moreover, Claim 15 recites the limitation "measuring the redox reaction" yet the claims fail to set forth the critical metes and bounds of this step. In order to particularly point out and distinctly set forth the subject matter which applicant regards as the invention, the claims must clearly define this reaction and how it is measured.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komori et al. (EP 1 002 874 A2, May 24, 2000) and Glossary of class names of organic compounds (PAC, 1995, 67, 1307 Glossary of class names of organic compounds, pages 1351 and 1396), in view of Benezra et al. (US Patent No. 5,468,640), and further in view of Ishimaru et al. (Patent No. 6,127,138).

Claims 11-15 are drawn to a method of measuring a glycated protein, the method comprising, treating a sample containing the glycated protein with a protease in the presence of a sulfonic acid compound, allowing a glycated portion of a glycated protein degradation product (obtained by the protease treatment) and a fructosyl amino acid oxidase to react with each other, and measuring the redox reaction, wherein the sulfonic acid compound is at least one selected from the group consisting of dodecylbenzenesulfonic acid sodium, wherein the protease is a metalloproteinase, wherein the redox reaction is measured by determining an amount of hydrogen peroxide generated by the reaction of the glycated portion of the glycated protein degradation product and the fructosyl amino acid oxidase, wherein the amount of the hydrogen peroxide is determined by using an oxidase to reduce the generated hydrogen peroxide and oxidize a substrate that develops color by oxidation and measuring a degree of the color that the substrate has developed, wherein the degree of the color is measured by measuring an absorbance at a wavelength for detecting the substrate, and the degree of the color is measured by measuring an absorbance at a wavelength for detecting the substrate.

Komori et al. teach a method of measuring the amount of a glycated protein in a sample (Abstract, and page 2 0003 and 0004), pre-treating a sample with a nitro and a sulfonic acid compound (a tetrazolium compound) (page 2 0010, page 3 0017, page 6 0045, page 7 0061, and page 11). It must be noted that a sulfonic acid compound is an organic compound having $HS(=O)_2OH$ formula, and a nitro compound have $-NO_2$ group which may be attached to carbon, nitrogen, or oxygen (see PAC, Glossary of class

names of organic compounds, pages 1369 and 1351). Therefore, the tetrazolium compound of Komori et al. could be considered as both a nitro and a sulfonic acid compound. Komori et al. teach the pretreated sample is treated with a protease (p.6 0050) (treating a sample containing the glycated protein with a protease in the presence of a sulfonic acid compound) (page 6 0045, page 7 0061). Komori et al. further teach to prepare a hemolyzed sample whole blood cells or blood cell fraction separated from whole blood may be hemolyzed using a surfactant (page 5 0043 and 0044). Komori et al. further teach a protease and degrading the glycated protein by a fructosyl amino oxidase to form hydrogen peroxide and measuring the quantity of hydrogen peroxide by measuring the degree of the color (0004, 0030, 0051), with a spectrophotometer (0059).

Komori et al. do not teach sulfonic acid compound is lithium lauryl sulfate, and the protease is a metalloproteinase. However, Benezra et al. teach using surfactant lithium lauryl sulfate for rapid and reliable determination of total hemoglobin in a whole blood sample (column 4 lines 24 and column 10 line 48). Benezra et al. teach the surfactant denatures the hemoglobin, the denaturation releases the hemes, and hemes are extracted into the micelles of the surfactant, where contact with atmospheric oxygen causes rapid oxidation of the heme iron to the ferric state. Subsequent reaction of the ferric heme with hydroxide ions leads to a reaction product, which is very stable as evidenced by retention of its absorption spectrum over a period of weeks (column 3 lines 23-37).

Moreover, Ishimaru et al. teach measuring an amount of glycated protein in a sample by treating the glycated protein with Protease N (a metalloproteinase) (Abstract

and Col.11, Table 2) in order to enhance the sensitivity of the detection (Col.5, Lines 59-63).

Therefore, in view of the above teachings, a person of ordinary skill in the art at the time the invention was made, could have been motivated to modify the method as taught by Komori et al. by substituting the sulfonic acid compound with the sulfonic acid compound as taught by Benezra et al. with predictable results of measuring the redox reaction. The motivation as taught by Benezra et al. would be rapid and reliable determination of hemoglobin in the sample and the stability of the reaction product. Moreover, a person of ordinary skill in the art at the time the invention was made could have been motivated to substitute the protease in the method of Komori et al. with the protease as taught by Ishimaru et al. with predictable results of obtaining a glycated protein degradation product. The motivation as taught by Ishimaru et al. would be to enhance the sensitivity of the detection. The claim method would have been obvious because substitution of one known sulfonic acid compound with another and a known protease with another would have yielded predictable results of obtaining a glycated protein degradation product and measuring the redox reaction to one of ordinary skill in the art at the time the invention was made.

Claims 8, 10, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komori et al. (EP 1 002 874 A2, Published June 24th, 2000) in view of Kaminagayoshi et al. (EP0158964 A2) and further in view of Armstrong (US Patent No.

4,102,810) and further in view of Johnson et al. (Blood, 1994, Vol.83, No.4, p.1117-1123).

Claims 8, 10, and 15 are drawn to a method of measuring a glycated protein, the method comprising, treating a sample containing the glycated protein with a protease in the presence of a sulfonic acid compound, allowing a glycated portion of a glycated protein degradation product (obtained by the protease treatment) and a fructosyl amino acid oxidase to react with each other, and measuring the redox reaction, wherein the sulfonic acid compound is dodecylbenzenesulfonic acid sodium, wherein the protease treatment is carried out in the presence of a sulfonic acid compound and a nitro compound, and wherein the nitro compound is at least one selected from the group consisting of 2, 4,-dinitrophenol.

As mentioned immediately above, Komori et al. teach a method of measuring a glycated protein (Abstract, and page 2 0003 and 0004) and (page 2 0010, page 3 0017, page 6 0045, page 7 0061, and page 11). Komori et al. further teach reducing substances such as glutathione (GSH) and the like present in erythrocytes may reduce the hydrogen peroxide or inhibit the redox reaction, and make the determination of the quantity of the glycated proteins inaccurate (page 2 0005).

Komori et al. do not teach the sulfonic acid compound is dodecylbenzenesulfonic acid sodium salt, and the nitro compound is sodium nitrite. However, Kaminagayoshi et al. teach the sulfonic acid compound and wetting agent sodium dodecylbenzenesulfonate (or dodecylbenzenesulfonic acid sodium salt). Kaminagayoshi et al. teach wetting agent serves to enable the body fluid in which the test piece is

immersed to uniformly wet the test piece (page 8 last paragraph and page 9 1st paragraph line 1).

Moreover, Armstrong teaches nitro compound sodium nitrite (lysing reagent)(column 3 Example 1, line15). Armstrong teaches a lysing reagent must release hemoglobin from the red cells to enable colorimetric determination (column 2 lines 3-6).

Further motivation is in Johnson et al. who teach using nitro compound 1-chloro-2,4-dinitrophenol (CDNB) to eliminate GSH in erythrocytes (p.1120, 2nd column 2nd and 4th paragraphs).

Therefore, in view of the above teachings a person of ordinary skill in the art at the time the invention was made could have been motivated to modify the method as taught by Komori et al. by substituting the sulfonic acid compound with the sulfonic acid compound as taught by Kaminagayoshi et al. with predictable results of measuring the glycated protein. The motivation would be to enable the sample containing the glycated protein in which the test piece is immersed to uniformly wet the test piece. Moreover, a person of ordinary skill in the art could have been motivated to modify the method as taught by Komori et al. by substituting the nitro compound with the nitro compound as taught by Armstrong with predictable results of releasing the glycated protein and measuring the redox reaction. The motivation would be to reduce substances such as glutathione and as taught by Armstrong to release hemoglobin from the red cells to enable colorimetric determination. The claim method would have been obvious because substitution of one known sulfonic acid compound with another and one known nitro compound with another would have yielded predictable results of measuring the redox

reaction and the glycated protein to one of ordinary skill in the art at the time the invention was made. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art. KSR, 550 U.S. at ___, 82 USPQ2d at 1395; Sakraida v. AG Pro, Inc., 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); Anderson 's-Black Rock, Inc. v. Pavement Salvage Co., 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp., 340 U.S. 147, 152, 87 USPQ 303, 306 (1950).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651